JUN 17 2010

Section 6 – 510(k) Summary

K110871

1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
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Date Prepared: March 24, 2010

2. Device Name:

Proprietary Name: GC Fit Checker Advanced
Classification Name: Dental Impression material
Device Classification: 872.3660
Product Code: ELW

Substantial equivalence for the medical device is based on comparison to the following devices:

Product	Applicant	510(k) No.	Code No
Fit Checker II	GC AMERICA, INC	K032289	ELW
GC Fusion Fast (Exa'lence)*	GC AMERICA, INC	K043471	ELW
GC Fusion (Exa'lence)*	GC AMERICA, INC	K041398	ELW
HYDROFLEX	GC AMERICA, INC	K973343	ELW

*Due to trademark issues, product was renamed Exa'lence from Fusion/Senn. FDA notified August 18, 2009.

3. Device description and Intended Use

GC Fit Checker Advanced is a silicone impression material intended to check fit by detecting the high spots and pressure points of crowns, bridges, veneers, inlays and dentures.

4. Components and Mode of Action

GC Fit Checker Advanced has two types of packaging/delivery systems in which the base silicone paste and the catalyst silicone are filled. One is in tubes and the other is a cartridge device, similar to silicone impression material.

Fit Checker Advanced was developed combining the technology of Fit Checker and vinyl polyether silicone impression material, EXA'Lence, to achieve higher hydrophilicity. Due to the improved hydrophilicity, the material easily and uniformly spreads and sets sharply under moist oral environment. The optimal translucency enables the users to examine the thickness with ease. This product reduces your stress during the fit checking process which is usually done repeatedly until a good fit is achieved.

5. Description of Safety and Substantial Equivalence

The applicant device, Fit Checker Advanced is equivalent to the predicate device, GC Fit Checker II, in its intended use. The applicant device, Fit Checker Advanced, is equivalent to the predicate device, EXA'lence Extra Light Body Regular set in its chemical composition.

5. Performance

1) Summary of Performance Specifications

	Specification	Test method applied	Test results		Requirement	Conforms
			GC Fit Checker Advanced	GC Fit Checker II		
1	Detail reproduction (μm)	Detail reproduction was measured by the detail reproduction test method in ISO 4823	20 20 20	20 20 20	20μm	Yes
2	Elastic recovery (%)	Elastic recovery was measured by the Elastic recovery test method in ISO4823	98.9 – 99.3	98.5 – 99.6	≥96.5	Yes
3	Strain in Compression (%)	Strain in compression was measured by the Strain in compression test method in ISO 4823	4.2 – 4.5	6.1 – 6.5	2.0-20	Yes

As described above, the applicant device, GC Fit Checker Advanced is substantially equivalent to comparative devices, such as GC Fit Checker II and EXA'lence.

4. Shelf Life Evaluation and Storage Conditions:

- Shelf Life 2 years
- Store in a cool and dark place. 4-25°C (39.2-77.0°F)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mark Heiss, DDS
Director –Academic and Regulatory Affairs
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

JUN 17 2011

Re: K110871
Trade/Device Name: GC Fit Checker Advanced
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: March 24, 2011
Received: March 29, 2011

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111087

Device Name: GC Fit Checker Advanced

Indications for Use:

Checking fit of crowns, bridges, veneers, inlays and dentures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111087